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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,337	07/26/2001	Satoshi Mori	55107	5232
21874	7590	10/20/2003	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 9169 BOSTON, MA 02209			FRONDA, CHRISTIAN L	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,337	MORI ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 8-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 6 is/are rejected.
- 7) ☒ Claim(s) 3,5 and 7 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restriction

1. Applicants' arguments filed 8/4/2003 regarding the election of one amino acid sequence for examination have been fully considered but they are not persuasive. Applicants' position is that the amino acid sequences of SEQ ID NOS: 1, 3, 5, 7, 9, 11, 13, 15, 17, 21, and 23 are members of a single genus because they have in common the concept of "enzyme exhibiting nicotianamine synthase activity" and that they have high homology to each other. The Examiner disagrees for reasons of record and the reasons stated below.

Each of the recited amino acid sequences are independent and patentably distinct inventions, and separate searches are required for each of the amino acid sequences. A search of all the inventions in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches that have different limits, boundaries, scope, and subject matter. A search for one specific amino acid sequence is not a search for any other amino acid sequence. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent subject matter, restriction for examination purposes is proper.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-7 and SEQ ID NO:1 are under consideration in this Office Action.

Claim Objections

3. Claims 3, 5, and 7 stand objected to because of the following informalities: Claims 3, 5, and 7 are objected to because they recite non-elected subject matter, specifically, SEQ ID NOS: 3, 5, 7, 9, 11, 13, 15, 17, and 21. Applicant is required to cancel the claim(s), or amend the claim(s) to recite the elected subject matter of SEQ ID NO: 1. Applicants have not provided arguments to traverse this objection. Thus, the objection stands for reasons of record.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention encompass any nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1 in which at least one amino acid has been replaced, deleted, or inserted into the sequence of SEQ ID NO: 1. The specification, however, only provides the following representative species encompassed by the invention: an isolated nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1. The specification also fails to provide a written description of the specific amino acid residues that must be deleted, replaced, or inserted to SEQ ID NO: 1 and the specific amino acid residues that must not be altered in order to preserve nicotianamine synthase activity. Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claims 2, 4, and 6 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

6. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1; does not reasonably provide enablement for any other embodiment.

The nature and breadth of the claims encompass for any nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1 in which at least one amino acid has been replaced, deleted, or inserted into the sequence of SEQ ID NO: 1.

Applicants' arguments filed 8/4/2003 have been fully considered but they are not persuasive. Applicants' position is that the specification provides assays to screen and search for the claimed invention. The Examiner disagrees for the reasons of record and the reasons stated below.

Teaching regarding searching or screening for the claimed invention is not teaching for making the claimed nicotianamine synthase. The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed nicotianamine synthase is enormous and entails selecting specific amino acid residues to change (deletion, insertion, substitution, or combinations thereof) in SEQ ID NO: 1 and determining by enzymatic assays

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whether the protein has nicotianamine synthase activity.

The specification does not provide guidance with respect to the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved. Thus, searching for the specific amino acid residues to change (deletion, insertion, substitution, or combinations thereof) in SEQ ID NO: 1 is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting protein has nicotianamine synthase activity is extremely low since no information is provided by the specification regarding the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved. Without such a guidance, the experimentation left to those skilled in the art is undue. Claims 2, 4, and 6 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

Claim Rejections - 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Higuchi et al. (Plant Physiol. 1999 Feb;119(2):471-80).

Higuchi et al. teach a nicotianamine synthase protein which has at least one amino acid that has been replaced, deleted, or inserted into the sequence of SEQ ID NO: 1 (see attached paper and alignment). Thus, the reference teachings anticipate the claimed invention.

Conclusion

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this

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Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF



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